

***Remarks***

Reconsideration of this Application is respectfully requested.

Claims 1-13, 18-21, 26, 29-32 and 34-40 are pending in the application, with claims 1, 2, 6, 7 and 26 being the independent claims.

Based on the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding rejections and that they be withdrawn.

***I. Double Patenting***

The Examiner has maintained the rejection of claims 1-13, 18-21, 26, 29-32 and 34-38 under the judicially-created doctrine of obviousness-type double patenting. (See Paper No. 23, Page 2.) Applicants respectfully traverse this rejection.

A recent Federal Circuit decision changes how double-patenting should be considered. *See Eli Lilly and Co. v. Board of Regents of the University of Washington*, 334 F.3d 1264 (Fed. Cir. 2003). The Federal Circuit deferred to the USPTO: "An agency's interpretation of its own regulations is entitled to substantial deference, and that interpretation will be accepted unless it is plainly erroneous or inconsistent with the regulation." *See id.* at 1266. Essentially, the Board and the Federal Circuit decided that a two-way test was appropriate for determining whether two patents could issue on the "same invention". Thus, unless the inventions were by two-way obviousness analysis the same invention, they were not to be considered the same invention.

Because the Director of the PTO's ("Director's") interpretation of 37 C.F.R. § 1.601(n) as establishing a "two-

"way" test for determining whether two parties are claiming the "same patentable invention" is neither plainly erroneous nor inconsistent with the regulation, and the Board committed no reversible error in applying the two-way test to determine that the '529 patent and the corresponding claims of the '663 reissue application do not define the same patentable invention, we affirm.

*Id.* at 1265. That is, two patents can issue and be enforced unless each is obvious over the other. (The same reasoning would apply to anticipation.) If two distinct parties can receive patents on the "same invention" by one-way analysis, then it is only fitting that a single party should be treated the same. Reconsideration and withdrawal of this rejection are respectfully requested.

Applicants respectfully submit that even if the above reasoning did not apply, it is premature to submit a Terminal Disclaimer at this stage. Until claims are final, the propriety of this rejection cannot be determined.

## ***II. Claim Rejections Under 35 U.S.C. § 102***

Claims 1, 2, 12, 13, 26 and 34-38 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by the DIFCO manual (1984) in light of Dyas *et al.*, *Photochemistry* 35:655-660 (1994) (hereinafter "Dyas"). (See Paper No. 23, page 3.) Applicants respectfully traverse this rejection.

Claim 1 recites several media components and concludes with the phrase: "wherein said medium is capable of supporting the cultivation of an animal cell *in vitro*."

The present Office Action maintained the rejection set forth in the previous Office Action. The previous Office Action had considered the above "wherein . . ." clause to be a statement of intended use. The present Office Action apparently accepts Applicants'

argument that ingredients necessary to cultivate animal cells are not taught in the DIFCO manual, but counters with an argument that the specification describes "a media that has ingredients that would be contained in the media taught by the DIFCO manual." Paper No. 23 at page 3.

Applicants respectfully assert that whether some ingredients are similar in make-up, and even concentration, to those taught in the DIFCO manual is irrelevant for a 35 U.S.C. §102(b) rejection. *See* Applicants' arguments set forth in the Reply filed on April 30, 2003, at page 3. Under 35 USC § 102, a claim can only be anticipated if every element in the claim is expressly or inherently disclosed in a single prior art reference. *See Kalman v. Kimberly Clark Corp.*, 713 F.2d 760, 771 (Fed. Cir. 1983), *cert. denied*, 465 U.S. 1026 (1984). An element in present claim 1 -- "wherein said medium is capable of supporting the cultivation of an animal cell *in vitro*" -- is clearly not disclosed in the DIFCO manual. Thus, regardless of any similarities between ingredients of the DIFCO manual and some ingredients of the presently claimed invention, the DIFCO manual cannot properly be said to anticipate the present invention.

The Office Action relied on an inference that potato agar "would contain amino acids, vitamins, trace element, etc. because these items are naturally present in potatoes and agar." Paper No. 23, page 3. What might naturally occur in potatoes is not in question because it is irrelevant to the present discussion. Animal cells have different requirements for cultivation than do bacteria and yeasts. It is clear in the art that many different media are available and used for different cell types. Thus even though there may be ingredients in common between two media, no skilled artisan would expect the media to have like performance in different cell types.

The Office Action concludes with the following statement:

Therefore, it still appears that the culture media taught by DIFCO anticipates the stated claims because it [sic] would contain the ingredients that applicant has indicated are needed to cultivate animal cells.

Paper No. 23, page 3. The observation that some requirements may overlap, *e.g.*, temperatures above freezing and below zero, presence of a food source and metabolites for growth, etc., does not indicate that all these cells have identical requirements. Thus, it is clearly incorrect to assume, just because one or more component present in one medium can also be found in another, that both media have the same capabilities of supporting cultivation. Reconsideration and withdrawal of this rejection are respectfully requested.

### ***III. Claim Rejections Under 35 U.S.C. § 103***

#### ***A. DIFCO Manual in light of Dyas in view of Gibco Catalogue***

Claims 1-5, 8-13, 26, 29-32 and 34-38 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over the DIFCO manual in light of Dyas, in view of Gibco BRL Life Technologies Catalogue and Reference Guide (hereinafter "Gibco Catalogue"). (*See* Paper No. 23, page 4.) Applicants respectfully traverse this rejection.

The DIFCO manual is applied as above. The Gibco Catalogue is referenced as showing that both lipoic acid and myristate can be added to a culture medium. The Office Action alleged that, based on this teaching, a person of ordinary skill in the art would reasonably assume that these ingredients could beneficially be added to the culture medium taught by the DIFCO manual. Applicants' previous arguments have been considered but were found non-persuasive.

The Office Action alleged:

The references show that it was known in the art at the time of the invention that all of applicant's claimed ingredients are used for the same purpose. Therefore, it is considered to be an obvious modification of what was known in the art at the time of the invention to combine the teachings of the references.

Paper No. 23, page 4. Applicants respectfully assert that a *prima facie* case of obviousness has not been established. The Office Action apparently ignored the case law cited in Applicants' previous reply. *See e.g., ACS Hosp. Sys., Inc. v. Montefiore Hosp.*, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984) (cited at page 8 of Applicants' October 15, 2002 Reply.) The Office Action has merely asserted obviousness based on erroneous presumptions and assumptions. The Office Action presumed or assumed:

- 1) that "the art" of the DIFCO manual and "the art" of the secondary reference were the same art. This is incorrect. Cell culture, while a general field of industry, is composed of several arts. For example, the art of culturing animal cells is distinct from the art of bacterial and yeast cell culture. *Media and techniques in these arts are not interchangeable.*
- 2) that all ingredients are used for the same purpose. This also is incorrect. If, as the Office Action presumes, all ingredients were present in media for the same purpose, then only a single ingredient would be needed, for example, water. For animal cells, water is a lysis agent; that is, placing an animal cell in water without a balancing osmotic force will cause rupture of the cell membrane. It is thus clear to one of ordinary skill in the art that all ingredients are not for the same purpose(s). Therefore, it is not obvious to

substitute one ingredient for the other or to mix and match ingredients based simply on availability or previous use in another application.

Based on the above, Applicants respectfully submit that no *prima facie* case of obviousness has been established. Reconsideration and withdrawal of this rejection are respectfully requested.

***B. U.S. Patent No. 5,122,469 in view of Dyas and Gibco Catalogue***

Claims 1-13, 18-21, 26, 29-32 and 34-38 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 5,122,469 (hereinafter "the '469 patent") in view of Dyas and the Gibco Catalogue. (See Paper No. 23, page 4.) Applicants respectfully traverse this rejection.

The Office Action employed two rationales to support this rejection. Applicants respectfully assert that each rationale cannot stand reasoned argument against it. Thus this rejection must be withdrawn.

The first rationale asserted in the Office Action is that use of potatoes to supply a hydrolysate to support cultivation is considered to be a product by process limitation. If such were the case, then the requirement for election of species causing the election of potato as species would be improper. The requirement has not been withdrawn, thus the Office still considers it proper. The only rationale for requiring the election would be that the species was relevant. Hence, there must be a difference in product depending on the species of material selected. It stands to reason that a hydrolysate or extract from a potato would be different from a hydrolysate or extract from another genus or species. Different environments and selective pressures over eons have evolved species differences, some

apparent and some not yet known. No reasonable artisan would avow that choice of species (possibly even strain) to use as material source would definitely not have an effect on a particular cell type to be grown. The expectation is that there would be a difference, rather than that there would be no difference. This expectation is supported by the election of species requirement still maintained in the present application.

The second rationale asserted by the Office Action is similar to that in the 35 U.S.C. §103 rejection above. Although the references are different, the argument is basically the same. No skilled artisan would consider all ingredients as interchangeable, *i.e.*, "for the same purpose" as asserted in support of the rejection. This rejection is therefore improper and must be withdrawn.

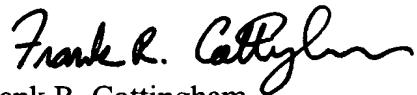
### ***Conclusion***

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Reply is respectfully requested.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

  
Frank R. Cottingham  
Attorney for Applicants  
Registration No. 50,437

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1100 New York Avenue, N.W.  
Washington, D.C. 20005-3934  
(202) 371-2600

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